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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,798	10/21/2003	Jay Edelberg	1676.001US2	5627

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EXAMINER
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MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/690,798

Applicant(s)

EDELBERG ET AL.

Examiner

Patricia C. Mallari

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 59-106 is/are pending in the application.
- 4a) Of the above claim(s) 59-73, 77 and 85-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74-76 and 78-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 and 09 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is a non-final Office action. New grounds of rejection have been introduced to reject claim 84. See the following rejection

#### ***Drawings***

A new drawing containing figure 10 was received on 3/19/06. These drawings are approved.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-76 and 78-84 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,750,376 to Weiss et al. Weiss describes in vitro or ex vivo modified stem cells (col. 15, line 64-col. 23, line 5 of Weiss). The cells can be coupled via an electrical interface to endogenous tissue or cells, can be implanted into a mammalian subject at a site distant from a natural site for physiological or pathophysiological function of a subject (col. 22, lines 56-60; col. 23, lines 37-45 of Weiss), can monitor a chemical, physiological, or pathophysiological function of the subject, and can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor (col. 22, lines 31-55 of Weiss). The applicants should note that the claim language fails to require

positively that the cells actually perform or be arranged as described above, only that they *can* or are *adapted* to perform or be arranged accordingly. The cells as described by Weiss certainly can perform or be arranged to perform as described. Claims 75 and 78-82 merely comment further on the recited capabilities. Furthermore, the term “implantable physiological or pathophysiological biosensor” on line 1 of claim 74, “are adapted to be coupled via an electrical interface to endogenous tissue or cells” on lines 3-4 of claim 74, and “are adapted to be implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject” on lines 4-5 of claim 74 are merely “intended use” language which cannot be relied upon to define over the prior art, since Weiss teaches all of the claimed structural limitations and their recited relationships. See *Ex parte Masham 2* USPQ 2<sup>nd</sup> 1647. The cells of Weiss are certainly capable of being used as such a sensor, are capable of being coupled via an electrical interface as recited, and are further capable of being implanted as recited.

Regarding claim 76, the stem cells are molecularly, genetically, or cellularly engineered (col. 18, line 43-col. 23, line 5 of Weiss).

Regarding claims 83 and 84, the modified stem cells are incorporated within a device, wherein the device may include, for example a substrate (example 11 of Weiss) or an injection cannula or needle (example 14 of Weiss). With further regard to claim 84, the device is a tube, wherein a cannula or needle is a tube.

### ***Response to Arguments***

Applicant's arguments filed 3/9/06 have been fully considered but they are not persuasive.

The applicants argue that Weiss does not anticipated claim 74 because Weiss teaches only stem cells and fails to teach a biosensor containing stem cells and an electrical interface. However, claim 74 only recites the stem cells be "adapted to be coupled via an electrical interface to endogenous tissue or cells." It is emphasized that the applicants have not positively recited that the stem cells *are* coupled via the electrical interface to the endogenous tissue or cells, only that they are "*adapted* to be coupled" (emphasis added). This language is only "intended use" language and cannot be relied upon to define over Weiss since the stem cells of Weiss appear to be capable of being coupled as described. The applicants have not shown that the stem cells of Weiss are not capable of being coupled in such a way, nor does the claim language or instant specification disclose any special feature which makes the claimed invention "adapted to be coupled" over the invention of Weiss. Column 22, lines 56-60 and column 23, lines 37-45 of Weiss were merely cited to show that the cells are adapted to be implanted into a mammalian subject at a site distant from a natural site. Therefore, the rejection of claims 74-76 and 78-83 as being anticipated by Weiss stands.

Applicant's arguments with respect to claim 84 have been considered but are moot in view of the new ground(s) of rejection.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Patricia Mallari  
Patent Examiner  
Art Unit 3735

  
Charles A. Marmor, II  
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